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DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 596-7700
FAX: (781)596-7896

WARNING LETTER
NWE-25-03W

VIA FEDERAL EXPRESS

September 17, 2003

R. Eric Montgomery
President
Oraceutical, LLC
815 Pleasant Street
Lee, MA 01238

Dear Mr. Montgomery:

An inspection of your facility located at 815 Pleasant Street, Lee, MA was initiated by an investigational team from the Food and Drug Administration (FDA) on June 30, 2003 and completed on July 8, 2003. This inspection verified that your firm manufactures and distributes medicated ear drops for veterinary use, such as Biotix and Clear. The labels for these products include claims that establish your products are intended to be used as drugs. Because your products are not the subject of approved New Animal Drug Applications (NADAs), they are unsafe under Section 512(a) of the Federal Food, Drug, and Cosmetic Act (the Act) and thus adulterated under Section 501(a)(5) of the Act.

Section 201(g)(1) of the Act defines a drug as any article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals. Section 201(v) of the Act defines a new animal drug as one which is not generally recognized among experts as safe and effective. New animal drugs may not be marketed in the absence of an approved NADA demonstrating the safety and effectiveness of the product.

Your products are labeled in part:

> Biotix: - "MEDICATED EAR DROPS WITH HYDROCORTISONE *** Aids in the Treatment of Bacteria, Fungus and Yeast Infections of the Ear *** BIOTIX contains 3 active enzymes and a peracetic acid system that have been shown to be antibacterial, antifungal and antiviral *** For Veterinary Use Only"

Clear: - "Cleaner and Medication All In One *** CLEAR contains 3 active enzymes and a peracetic acid system that have been shown to be antibacterial, antifungal and antiviral"

Based on the above labeling, the marketing of these products violates the Act.

The representations on the labeling for both of these products indicate that the products are intended for use in the prevention of disease in animals and that they are intended to affect the structure or function of animals. The products are therefore drugs under section 201(g)(1) of the Act. The products are also "new animal drugs" under section 201(v) of the Act because FDA is not aware of any scientific evidence showing the products are generally recognized as safe and effective.

Because none of the products listed above are covered by an approved NADA, as required by section 512(a)(1)(A) of the Act, the products are unsafe under section 512(a) and thus adulterated pursuant to section 501(a)(5) of the Act; they are being illegally marketed.

This letter is not intended to be an all-inclusive review of the products your firm markets. It is your responsibility to ensure adherence to all applicable regulations and provisions of the Act.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Possible actions include seizure and/or injunction.

You should notify this office in writing, within fifteen (15) working days of the receipt of this letter of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed.

You may direct your reply to Karen N. Archdeacon, Compliance Officer, at the address noted above. If you have any questions concerning this matter, please contact Ms. Archdeacon at (781) 596-7707.

Sincerely,

Gail T. Costello
District Director
New England District Office

Cc: Landco
Golden Crown Corporation
75 Thornton
Post Falls, ID 83854